

Title: **Quality Control Record Sheet
Fast IA-2 Ab ELISA Kit QC Data**

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Approved by: **L CARR**

Kit lot number: FKIE175A Kit expiry date: 08 December 2025

Kit manufacture date: 09 December 2024

Reagent Lot Numbers:

IA-2 Coated Wells: <u>IE237</u>	Expiry date: <u>16 MAR 2026</u>
IA-2-Biotin: <u>IEB166</u>	Expiry date: <u>15 APR 2026</u>
Recon. Buffer for IA-2-Biotin: <u>IBB186</u>	Expiry date: <u>18 MAR 2026</u>
Streptavidin Peroxidase: <u>GEP673</u>	Expiry date: <u>21 APR 2026</u>
Diluent for SA-POD: <u>PB182</u>	Expiry date: <u>27 JUN 2026</u>
Reaction Enhancer: <u>IES130</u>	Expiry date: <u>03 OCT 2026</u>
Peroxidase Substrate: <u>PTS185S</u>	Expiry date: <u>27 APR 2027</u>
Stop Solution: <u>HESP134</u>	Expiry date: <u>19 AUG 2026</u>
Concentrated Wash Solution: <u>CW410</u>	Expiry date: <u>20 FEB 2027</u>
Calibrators: <u>IC175a</u>	Expiry date: <u>08 DEC 2025</u>
Controls: <u>INC175a/IPC175a</u>	Expiry date: <u>08 DEC 2025</u>

Curve and Controls: Incubation temp: +21 °C

Calibrator Concentration (units per mL)	Absorbance at 450 nm	Absorbance at 405 nm
Negative control	0.088	0.025
7.5	0.149	0.042
35	0.394	0.112
120	1.693	0.488
350	>4	1.620
4000	>4	2.445

Control	Absorbance at 450 nm	Absorbance at 405 nm	Concentration at 450 nm (units per mL)	Concentration at 405 nm (units per mL)	Range (units per mL)
Positive I	1.735	0.499	121.8	121.7	125 ± 40

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay performed by: Fiona Rylie
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Date: 29 October 2024

Authorised by: DR G Flood
Signature: *G Flood*
Position: Head of Quality Control
Date: 22nd Nov 2024